K110239

JUN 23 2011

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, Address, and Contact

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Contact: Bernice Lin, Ph.D.
VP Operations

Device Name and Classification

Classification Name:	Enzyme Immunoassay, Cannabinoids Class II, DLJ (91 Toxicology), 21 CFR 862.3870
	Cannabinoids Calibrators, Class II, DLJ (91 Toxicology), 21 CFR 862.3200
	Cannabinoids Controls, Class I, LAS (91 Toxicology), 21 CFR 862.3280
Common Name:	Homogeneous Cannabinoids Enzyme Immunoassay
Proprietary Name:	LZI Cannabinoids (cTHC) Enzyme Immunoassay, LZI Cannabinoids (cTHC) Drugs of Abuse (DAU) Calibrators LZI Cannabinoids (cTHC) Drugs of Abuse (DAU) Controls

Legally Marketed Predicate Device(s)

The LZI Cannabinoids (cTHC) 25, 50, and 100 Enzyme Immunoassays (EIAs) are substantially equivalent to the Lin-Zhi International, Inc. Cannabinoid (THC) Enzyme Immunoassay, Calibrators and Controls for Hitachi 717 Systems (k021887 & k021449) manufactured by Lin-Zhi International, Inc. The LZI Cannabinoids (cTHC) 25, 50, and 100 Enzyme Immunoassays are identical or similar to their predicate in terms of intended use, method principle, device components, and clinical performance.

Device Description

The LZI Cannabinoids (cTHC) 25, 50, and 100 assays are a homogeneous enzyme immunoassay with ready-to-use liquid reagent. The assays are based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent. Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, cannabinoid derivative -labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when free drug is present in the sample, antibody would bind to free drug, the unbound cannabinoid derivative -labeled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at 340 nm.

The LZI Cannabinoids (cTHC) 25, 50, and 100 Enzyme Immunoassays are kits comprised of two reagents, an R_1 and R_2 which are bottled separately but sold together within each kit.

The R_1 solution contains a mouse monoclonal anti-cannabinoid antibody, glucose-6-phosphate (G6P) nicotinamide adenine dinucleotide (NAD), stabilizers, and sodium azide (0.09%) as a preservative. The R_2 solution contains glucose-6-phosphate dehydrogenase (G6PDH) labeled with a cannabinoid derivative in buffer with sodium azide (0.09%) as preservative.

The LZI Cannabinoids (cTHC) 25 Enzyme Immunoassay calibrators and controls contain 0, 12.5, 18.75, 25, 31.25, 37.5, and 50 ng/mL of 11-nor-Δ^9-THC-9-COOH in human urine with sodium azide (0.09%) as preservative. These seven calibrators and controls are sold as individual bottles.

The LZI Cannabinoids (cTHC) 50 Enzyme Immunoassay calibrators and controls contain 0, 25, 37.5, 50, 62.5, 75, and 100 ng/mL of 11-nor-Δ^9-THC-9-COOH in human urine with sodium azide (0.09%) as preservative. These seven calibrators and controls are sold as individual bottles.

The LZI Cannabinoids (cTHC) 100 Enzyme Immunoassay calibrators and controls contain 0, 50, 75, 100, 125, 150, and 200 ng/mL of 11-nor-Δ^9-THC-9-COOH in human urine with sodium azide (0.09%) as preservative. These thirteen calibrators and controls are sold as individual bottles.

Intended Use

The LZI Cannabinoids (cTHC) 25, 50, and 100 Enzyme Immunoassays are intended for the qualitative and semi-quantitative determination of Cannabinoids in human urine using 11-nor-Δ^9-THC-9-COOH (the major metabolite of THC referred to here as cTHC) as calibrator at the cutoff values of 25, 50, or 100 ng/mL. The assays are designed for professional use with a number of automated clinical chemistry analyzers.

The semi-quantitative mode is for purposes of (1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GCMS or (2) permitting laboratories to establish quality control procedures.

The LZI Cannabinoids (cTHC) Drugs of Abuse (DAU) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Cannabinoids (cTHC) Enzyme Immunoassay.

The LZI Cannabinoids (cTHC) Drugs of Abuse (DAU) Controls are for use as assayed quality control materials to monitor the precision of the LZI Cannabinoids (cTHC) Enzyme Immunoassay.

The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Lin-Zhi International Inc.
c/o Ms. Bernice Lin
Vice President Operations
670 Almanor Avenue
Sunnyvale, CA 94085-2917

JUL 27 2011

Re: k110239
Trade Name: LZI Cannabinoids (cTHC) Enzyme Immunoassay,
LZI Cannabinoids (cTHC) Drugs of Abuse (DAU) Calibrator,
LZI Cannabinoids (cTHC) Drugs of Abuse (DAU) Controls
Regulation Number: 21 CFR § 862.3870
Regulation Name: Cannabinoid Test System.
Regulatory Class: Class II
Product Codes: LDJ, DLJ, LAS
Dated: June 08, 2011
Received: June 08, 2011

Dear Ms. Lin:

This letter corrects our substantially equivalent letter of June 23, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Premarket Notification

Indications for Use Statement

510(k) Number (if known): ____k110239_____

Device Name: Cannabinoids (cTHC) Enzyme Immunoassay
Cannabinoids (cTHC) Calibrators and Controls

Indications for Use:

The LZI Cannabinoids (cTHC) Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of Cannabinoids in human urine using 11-nor-Δ9-THC-9-COOH (the major metabolite of THC referred to here as cTHC) as calibrator at the cutoff values of 25, 50, or 100 ng/mL. The assay is designed for prescription use with a number of automated clinical chemistry analyzers.

The semi-quantitative mode is for the purposes of (1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC/MS or (2) permitting laboratories to establish quality control procedures.
The Cannabinoids (cTHC) Drugs of Abuse (DAU) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Cannabinoids (cTHC) Enzyme Immunoassay.

The Cannabinoids (cTHC) Drugs of Abuse (DAU) Controls are for use as assayed quality control materials to monitor the precision of the LZI Cannabinoids (cTHC) Enzyme Immunoassay.

The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive

Prescription Use __√__ AND/OR (Part 21 CFR 801 Subpart D) **Over-The-Counter Use _____ (21 CFR 807 Subpart C)**

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
(Per 21 CFR 801.109)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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